

Chapter 40

Biopharma Drugs Innovation in India and Foreign Investment and Technology Transfer in the Changed Patent Regime

Rakhi Rashmi
University of Nice, France

ABSTRACT

This chapter addresses the relationship between the intellectual property rights and Foreign Direct Investment in the context of Indian biopharma Industry to assess the impact of the TRIPs agreement of WTO on the biopharmaceutical industry of developing countries. The central issue in this study is the extent to which patent reform (after the imposition of the TRIPs agreement in 1995) affects India's ability to attract technology transfer for biopharmaceutical drugs innovation. The study analyzes FDI flow in the biopharma industry in Pre TRIPs (before the imposition of product patent protection 1991-1999) and post TRIPs (after product patent protection, 1999-2005). It does a comparative analysis of the relationship between the amount of foreign investment in different Indian states and the investment climate ranking of those states that are the part of Indian bio cluster.

1 INTRODUCTION

Trade related aspects of Intellectual Property Rights (TRIPs) agreement of the World Trade Organization (WTO) are considered to be one of the milestones in the international harmonization of patent protection. Product patent protection

has been imposed on all its member countries by its Article-27.1.¹ Article-27.1 places a strict obligation on member to provide patents for all patentable pharma and biopharma products. After the start of enforcement of the TRIPs agreement, there has been a significant change in the patent regime in the developing countries. Before TRIPs, a vast majority of developing countries such as

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Argentina, China, India, Korea and Mexico protected process but not product.

After the enforcement of the TRIPs agreement, these countries are no longer allowed to carry out reverse engineering (Lanjouw 2000). In reverse engineering the new chemical entity or molecule is manufactured with a new process whose development cost is minimal and clinical testing is not required. It has cost the developers several hundred million dollars to discover, develop and gain regulatory approval for a new medicine, even before incurring costs for development of the new drug molecule (A Maria et al; 2004).

After the imposition of product patent protection, generic production of new biopharmaceutical drugs (i.e. those patented post 2005) are not allowed and Indian firms must innovate novel biopharma drugs. The Indian biopharmaceutical industry is basically a biogeneric (Therapeutic products based on genetically engineered or recombinant technologies that are already in the market at least in some industrialized countries - Maria and Ramani; 2004) industry. India is the supplier of cheap generic drugs to the world. Main innovator products which have been produced as biogeneric drugs by the Indian biogeneric industry are Erythropoietin, G-CSF, recombinant Hepatitis B vaccine, Insulin, Interferon Alfa, streptokinase, among others.

The Indian generic drug industry grew to meet the drug needs of the country, and the government permitted it to ignore international patent protection law. The heavy burden of diseases in India comprises 18% of worldwide mortality and 20% of worldwide morbidity (WHO; 2003). However, it has limited resources to innovate novel drugs, since India's resources are 2% of world GDP and it invests just 1% the world healthcare investment (Sheena Reddy; 2006). As of 2006, the generic biopharmaceutical industry of a developing nation like India does not have the monetary resources to innovate novel drugs on its own. FDI and foreign technology transfer is essential to India's entry into the chain of novel drug innovation.

This gives an important situation to study the impact of the TRIPs agreement on the biopharma drug innovation in India by foreign technology transfer. So, the study is concentrated on the Indian biopharmaceutical industry and attempts to analyze the effect of the product patent protection on the foreign technology transfer in biopharmaceutical (Biopharmaceuticals are the large molecule drugs produced using rDNA technology e.g. Interferon, human growth hormone, human insulin - Arundel and Mintz; 2004) drugs innovation.

Also, it has been argued by the developed countries that strengthening of patent protection will bring innovation through increased foreign direct investment and greater transference of technology in developing countries. The objective of the TRIPs agreement, stated in Article 7 says; Protection and enforcement of Intellectual Property Rights should contribute to the promotion of:

Technological innovation and transfer and dissemination of technology to the mutual advantage of producer and user of the technological knowledge.

Thus, it can be interpreted that implementation of Art 27.1 will lead to greater foreign technology transfer in Pharma and biopharma sector. In Doha declaration too (Art 37)² it was agreed that the WTO would set up a working group to examine the relationship between trade and transfer of technology and to report findings to the fifth session of the Ministerial Conference (Art 38, 41).³

In this way the relationship of two very Articles (Article 7 and 27) is interesting to analyze as the same will measure the relationship between the intellectual property rights and FDI in the context of Indian biopharma Industry in order to know the impact of TRIPs agreement on the biopharmaceutical industry of developing countries.

These have been investigated in the first part of the chapter by analyzing the trend of foreign investment and transfer of technology in Indian biopharma sector as an effect of product patent regime.

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